

ETOLAC (Eye Drops)

KETOROLAC TROMETHAMINE USP

Compositions:

Each ml contain Ketorolac Tromethamine USP 5 mg.

Pharmacology:

Etolac is a sterile ophthalmic solution of Ketorolac tromethamine. It is a non-steroidal anti-inflammatory drug which has analgesic, anti-inflammatory, and anti-pyretic activity. The mechanism of its action is thought to be due to its ability to inhibit prostaglandin biosynthesis.

Dosage And Administration:

The recommended dose of ketorolac tromethamine solution is one drop (0.25 mg) four times a day for relief of ocular itching (inflammation & redness) due to seasonal allergic conjunctivitis and as needed for pain and photophobia for up to 3 days after incisional refractive surgery. For the treatment of postoperative inflammation in patients who have undergone cataract extraction, one drop should be applied to the affected eye(s) four times daily beginning 24 hours after cataract surgery and continuing through the first 2 weeks of the post-operative period.

Contraindications:

It is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formulation.

Warning And Precaution:

Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs and should be closely monitored for corneal health.

Side Effects:

The most frequent adverse events are transient stinging and burning on instillation. These events were reported by up to 40% of patients participating in clinical trials. Other adverse events occurring approximately 1% to 10% of the time during treatment with ketorolac tromethamine ophthalmic solutions included allergic reactions, corneal edema, iritis, ocular inflammation, ocular irritation, superficial keratitis and superficial ocular infections. Rarely reported adverse event included: corneal ulcer, eye dryness, headaches, and visual disturbance (blurry vision).

Use in Pregnancy and Lactation:

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Ketorolac Tromethamin solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Lactation:** It is not known whether ketorolac tromethamine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ketorolac Tromethamin is administered to a nursing mother.

Drug Interaction:

Specific drug interaction studies have not been conducted with ketorolac Tromethamine solution.

Overdosage:

If over dosage with Ketorolac Tromethamine occurs, treatment should be symptomatic.

Storage:

Store in a cool and dry place, away from light Keep out of reach of children.

Packing:

Etolac Eye Drops : 5 ml sterile solution in plastic dropper bottle.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.